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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/450,609 11/30/99 WEIBEL

H 5739.200-US

EXAMINER

HM22/0703

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ART UNIT

PAPER NUMBER

1617

DATE MAILED:

07/03/01

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/450,609

Applicant(s)

WEIBEL ET AL.

Examiner

Jennifer M Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7,9,11-13,16 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7,9,11-13,16 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

The rejection of claim 9 of record under 35 U.S.C. 112, second paragraph is hereby expressly withdrawn in view of Applicants' amendment.

Applicants' arguments filed April 23, 2001 have been fully considered but they are not persuasive.

Applicants' argue that the pharmaceutical composition of claim 6 is not described or suggested by either cited prior art references and has improved stability.

However, Applicants' attention is drawn to the example on page 35 of the Lohray reference (WO 97/41097) of record, where it teaches Applicant's composition comprising **lactose, magnesium stearate, cellulose** and corn starch, prepared with **drying** under reduced pressure. The difference between above reference and Applicant's claiming invention is the usual pharmaceutically acceptable excipients such as talc, lactose being employed is anhydrous and the specific cellulose. Applicants' are claiming a well known composition modified with **usual**, pharmaceutically acceptable excipients routinely incorporated in a tablet form in a low water content. The Lohray reference prepared the

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composition employing process of drying the mixtures under the reduced pressure. Therefore, Lorhray's composition obviates Applicants' composition of low water content, without showing result of improved stability alleged by the Applicants.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

It is suggested that Applicants submit a declaration to clearly establish a surprising and unexpected result using Applicants teaching.

In view of the above Office Action of November 22, 2000 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

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Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 6, 7, 9, 11-13, 16, and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al.(WO 9741097) in view of Sohda et al.(U.S.Patent No.5972971).

Lohray et al. teaches at page 35, example, applicants' composition in a tablet form.

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Lohray et al. at page 34, lines 27-29, page 35, example, and page 7, lines 13-14, teach pharmaceutical composition containing applicants' active agent in tablet, capsule, or powder form, in combination with the pharmaceutically acceptable excipient set forth in claims 8-10, and flavourants, sweeteners set forth in claim 16, and other media normally employed in preparing such compositions.

Sohda et al. at abstract and column 10, lines 20-21, teach anti-diabetic agent containing anti-oxidants, preferably ascorbic acid. Sodha et al. also teach at column 9, lines 55-65, the anti-diabetic agent containing applicants' excipient such as lactose, mannitol, starch, crystalline cellulose, silicone dioxide, magnesium stearate, and hydroxy propyl methyl cellulose.

The difference between the primary reference and applicants' claimed invention is the presence of anti-oxidant set forth in claims 6, 14, and 15, and the proportions set forth in claims 8 and 9. However, to incorporate anti-oxidant to the primary reference would have been obvious to a person of ordinary skill in view of Sohda et al. who teach antidiabetic agent containing anti-oxidant and the other excipient. One of ordinary skill in the art would have been motivated to combine anti-oxidants to the above composition since Lohray et al. teach other media normally employed can be incorporated and anti-

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oxidant is normally incorporated by Sohda et al. in formulating anti-diabetic agent.

The proportions of active agents to be used, and adjusting water content of excipient are all deemed obvious since they are all within the knowledge of the skilled pharmacologist.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

It is suggested, to advance the prosecution of the subject application, that a side by side comparison of stability be performed and results submitted per Rule 1.132 for review by the Patent Office.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

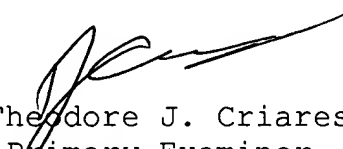
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is (703) 308-2232. The examiner can normally be reached on Monday through Friday from 9 AM. to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-4612. The fax phone number for the

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organization where this application or proceeding is assigned is
(703) 308-4556.

Any inquiry of a general nature or relating to the status
of this application or proceeding should be directed to the
receptionist whose telephone number is (703) 308-1235.



Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
June 27, 2001